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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/080,140 05/15/98 BILLING-MEDEL

P 6105.US.P1

023492
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HM12/0705

EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/080,140

Applicant(s)
Billing-Medel et al

Examiner
Kar n Canella

Art Unit
1642



-- Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-73 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 58-62, 64-67, and 71-73 is/are allowed.
- 6) ☒ Claim(s) 45-57, 63, and 68-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

Response to Amendment

1. Claims 10-16, 25, 30, 33, 35, 38 and 39 have been canceled. Claims 45-73 have been added.

New Claim Rejections

2. Claims 45-57 and 63, 68, 69 and 70 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record given in paragraphs 7 and 8 of Paper No. 4. The specification, while being enabling for purified polynucleotides comprising SEQ ID NO:1-12 and purified polynucleotides encoding SEQ ID NO:25-29 and degenerate coding sequences thereof, does not reasonably provide enablement for purified polynucleotides having 95% identity over the entire length of SEQ ID NO:1-12 or a polynucleotide encoding a polypeptide having 95% sequence identity to SEQ ID NO:25 or a polynucleotide encoding an antigenic determinant or an epitope.

Claims 45-57 are drawn to polynucleotide variants of the disclosed polynucleotide sequences or polynucleotide encoding proteins having at least 95% sequence identity to SEQ ID NO:25. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. As stated in paragraph 7 of Paper No. 4, the specification does not teach how to use polynucleotide variants of SEQ ID NO:1-12 in the detection of prostate cancer and that a substantial number of the polynucleotides encompassed by the claims would not share either structural or functional properties with PS116.

Claims 49, 52, 53, 63, 68, 69 and 70 are drawn to a polynucleotide encoding an antigenic determinant and are rejected for the reasons of record stated in paragraph 8 of Paper No. 4. Applicant has provided exhibit D in an attempt to establish that the determination of an antigenic determinant or an epitope is routine in the art. Exhibit D has been considered but not found persuasive as the examiner contends that identification of an epitope cannot be anticipated by the amino acids sequence and must be done empirically (as concluded from the teachings of Paul, Klein and Ristori, pp. 6-7, paragraph 8 of Paper No. 4), necessitating undue experimentation and further, the specification has not disclosed a single antigenic portion of the encoded peptides.

3. All other rejections and objections as stated in Paper No. 16 are withdrawn.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



ANTHONY C. CAPUTA
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TECHNOLOGY CENTER 1600

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
July 1, 2001